

Atty Dkt No. 0243.04

USSN 10/821,055

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### Introductory Comments

#### Overview of the Amendments to the Claims.

Claims 1-30 are pending in the application. Claims 20 and 24 are canceled herein. Claims 1, 10, 11, 15-19, 21-23, and 25-30 are amended herein. Cancellation or amendment of these claims is done without prejudice or disclaimer. Applicants expressly reserve the right to bring the subject matter of the original claims again in a subsequent, related application. New claims 31-53 are added by this amendment. Claims 1-19, 21-23, and 25-53 are pending after entry of this amendment. The amendments to the claims are presented herein below (after the signature page) in the section titled "Amendments to the Claims."

Support for the amendment to claim 1 can be found throughout the specification, for example, at the following locations: page 7, line 19, to page 8, line 24; page 9, lines 3, to page 10, line 8; page 12, lines 7-29; page 17, line 24, to page 19, line 22; Figure 3 (e.g., col. 5, EVENT CODE, and col. 6, BG READING); page 33, line 7, to page 34, line 24; and page 35, lines 7-16.

Support for the amendment to claim 10 can be found throughout the specification, for example, at the following location: page 4, lines 4-6.

Claim 11 has been amended to change claim dependency.

Support for the amendment to claim 15 can be found throughout the specification, for example, at the following locations: page 7, line 19, to page 8, line 24; page 9, lines 3, to page 10, line 8; page 12, lines 7-29; page 17, line 24, to page 19, line 22; Figure 3 (e.g., col. 5, EVENT CODE, and col. 6, BG READING); page 33, line 7, to page 34, line 24; and page 35, lines 7-16.

Claims 16-19, 21-23, 25, 26, 28-30 have been amended to provide proper antecedent basis for the terms therein. Claim 25 has been amended to change claim dependency. Claim 29 has also been amended to correct a minor typographical error.

Support for the amendment to claim 27 can be found throughout the specification, for example, at the following locations: page 21, lines 15-26; and page 29, lines 14-15.

Support for new claims 31-37 can be found throughout the specification, for example, at the following locations: page 18, line 16, to page 19, line 15; page 41, line 14, to page 42, line 9; and page 45, line 11, to page 49, line 5.

Support for new claims 38-53 can be found throughout the specification as originally

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filed, for example, at the following location: page 35, line 3, to page 36, line 10.

Accordingly, no new matter has been added by way of this amendment and the entry thereof is respectfully requested.

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**AMENDMENTS TO THE CLAIMS**  
**(including complete listing of the claims)**

1. (Currently Amended) A method of formulating one or more analyte data  
5 databases, said method comprising:

collecting analyte measurement values from one or more subject using an  
analyte monitoring device, comprising a sensing device, for each subject; and said  
analyte monitoring device ~~(i) comprising a transdermal sampling device, and (ii)~~  
~~providing~~ providing (i) frequent analyte measurement values, wherein said analyte  
10 measurement values comprise acquired data points that are specifically related to  
analyte amount or concentration in the subject; (ii) one or more data attributes, and  
(iii) one or more error messages related to skipped analyte measurement values; and

formulating said one or more analyte data databases by associating each of  
said data points and each of said one or more error messages related to skipped  
15 analyte measurement values with one or more data attributes.

2. (Original) The method of claim 1, wherein said data points further  
comprise derived data determined from one or more acquired data points and the  
derived data are associated with the data points from which they are derived.  
20

3. (Original) The method of claim 2, wherein each of said derived data are  
associated with one or more data attributes.

4. (Original) The method of claim 1, wherein said analyte measurement values  
25 are collected from a single individual.

5. (Original) The method of claim 1, wherein said analyte measurement  
values are collected from more than one individual.

30 6. (Original) The method of claim 5, wherein said formulating further

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comprises compiling multiple databases from each database where the data points are collected from a single individual and the data points for each single individual are associated with one or more relevant data attributes.

5           7. (Original) The method of claim 1, wherein said analyte is a biological analyte.

8. (Original) The method of claim 7, wherein said biological analyte is glucose.

10

9. (Original) The method of claim 2, wherein said analyte is glucose and said derived data comprises glucose amount or concentration.

10. (Currently Amended) The method of claim 9, wherein said analyte  
15 monitoring device is a glucose monitoring device, said glucose monitoring device comprising a ~~transdermal sampling device~~, a sensing device, a display, and means to provide an audible alert when glucose levels in a subject being monitored are outside of a predetermined range.

20           11. (Currently Amended) The method of claim ~~10~~1, wherein said acquired data points comprise electrochemical signals.

12. (Original) The method of claim 11, wherein said data attributes are selected from the group consisting of: chronological information, user perspiration  
25 levels, device operating temperature, missed measurements; skipped measurements, user body temperature, user skin conductance, environmental variables, alarm events, activity codes, total excursion, mean value, statistical function, subject code, demographic information, physical characteristics, and disease-associated characteristics.

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13. (Original) The method of claim 1, wherein said analyte monitoring device is capable of measuring more than one analyte.

14. (Original) The method of claim 13, wherein one of said analytes is  
5 glucose.

15. (Currently Amended) ~~An one or more analyte data databases, comprising~~  
~~formulated from data points collected using an analyte monitoring device,~~  
~~comprising a sensing device, wherein said analyte monitoring device (i) comprising a~~  
10 ~~transdermal sampling device, and (ii) providing provides (i) frequent analyte~~  
~~measurement values, and wherein said analyte measurement values comprise data~~  
~~points that are specifically related to analyte amount or concentration, and (ii) one or~~  
~~more data attributes;~~

one or more data attributes; and  
15 ~~one or more error messages related to skipped analyte measurement values,~~  
~~wherein the data points and each of said one or more error messages related to~~  
~~skipped analyte measurement values are associated with one or more relevant data~~  
~~attributes.~~

20 16. (Currently Amended) The one or more databases of claim 15, wherein  
said data points further comprise derived data determined from one or more acquired  
data points and the derived data are associated with the data points from which they  
are derived.

25 17. (Currently Amended) The one or more databases of claim 16, wherein  
each of said derived data are associated with one or more data attributes.

18. (Currently Amended) The one or more databases of claim 15, wherein  
said analyte measurement values are collected from a single individual.

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19. (Currently Amended) The one or more databases of claim 15, wherein  
said analyte measurement values are collected from more than one individual.

20. (Canceled)

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21. (Currently Amended) The one or more databases of claim 15, wherein  
said analyte is a biological analyte.

22. (Currently Amended) The one or more databases of claim 21, wherein  
10 said biological analyte is glucose.

23. (Currently Amended) The one or more databases of claim 16, wherein  
said analyte is glucose and said derived data comprises glucose amount or  
concentration.

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24. (Canceled)

25. (Currently Amended) The one or more databases of claim ~~24~~15, wherein  
said acquired data points comprise electrochemical signals.

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26. (Currently Amended) The one or more databases of claim 25, wherein  
said data attributes are selected from the group consisting of: chronological  
information, user perspiration levels, device operating temperature, missed  
measurements; skipped measurements, user body temperature, user skin conductance,  
25 environmental variables, alarm events, activity codes, total excursion, mean value,  
statistical function, subject code, demographic information, physical characteristics,  
and disease-associated characteristics.

27. (Currently Amended) The one or more databases of claim 15, wherein  
30 ~~said analyte monitoring device is capable of measuring~~ said analyte measurement

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values comprise analyte measurement values for more than one analyte.

28. (Currently Amended) The one or more databases of claim 27, wherein one of said analytes is glucose.

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29. (Currently Amended) A method of manipulating ~~an~~ one or more analyte data databases, comprising

providing the one or more analyte data databases of claim 15; and

manipulating said data points via said attributes associated with said data points to  
10 determine relationships between said data points and said attributes.

30. (Currently Amended) A method of manipulating ~~an~~ one or more analyte data databases, comprising

providing the one or more analyte data databases of claim 15; and

15 manipulating said attributes via said data points associated with said attributes to determine relationships between said attributes and said data points.

31. (New) The method of claim 1, wherein one or more of said analyte measurement values, one or more of said error messages, and one or more of said data attributes are transferred to a server via a network.  
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32. (New) The method of claim 31, wherein said formulating is carried out on said server.

25 33. (New) The method of claim 31, wherein said server communicates with said analyte monitoring device.

30 34. (New) The method of claim 29, wherein said one or more analyte databases are located on a network database server.

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35. (New) The method of claim 34, wherein said manipulating is carried out on said network database server.

5 36. (New) The method of claim 30, wherein said one or more analyte databases are located on a network database server.

37. (New) The method of claim 36, wherein said manipulating is carried out on said network database server.

10 38. (New) The method of claim 1, wherein said one or more data attributes associated with said data point or said skipped measurement value is one or more data attribute provided by the analyte monitoring device.

15 39. (New) The method of claim 38, wherein said one or more data attributes are selected from the group consisting of chronological information, user perspiration level, device operating temperature, user body temperature, user skin conductance, environmental variable, number of alarm events, and type of alarm events.

20 40. (New) The method of claim 1, wherein said one or more data attributes associated with said data point or said skipped measurement value is one or more data attribute comprising a user input.

25 41. (New) The method of claim 40, wherein said one or more data attributes are selected from the group consisting of activity codes, sleep and administration of medications, dose of medications, and times of medications.

42. (New) The method of claim 1, wherein said one or more data attributes associated with said data point or said skipped measurement value is one or more data identifier.

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43. (New) The method of claim 43, wherein said one or more data identifiers is selected from the group consisting of maximum analyte values, minimum analyte values, hypoglycemic analyte values, and hyperglycemic analyte values.

5        44. (New) The method of claim 1, wherein said one or more data attributes associated with said data point or said skipped measurement value is one or more subject identifier.

10       45. (New) The method of claim 44, wherein said one or more subject identifiers is selected from the group consisting of a subject code, demographic information, physical characteristic, selected aspects of the subject's medical history, and disease-associated characteristics.

15       46. (New) The one or more databases of claim 15, wherein said one or more data attributes associated with said data point or said skipped measurement value is one or more data attribute provided by the analyte monitoring device.

20       47. (New) The one or more databases of claim 46, wherein said one or more data attributes are selected from the group consisting of chronological information, user perspiration level, device operating temperature, user body temperature, user skin conductance, environmental variable, number of alarm events, and type of alarm events.

25       48. (New) The one or more databases of claim 15, wherein said one or more data attributes associated with said data point or said skipped measurement value is one or more data attribute comprising a user input.

30       49. (New) The one or more databases of claim 48, wherein said one or more data attributes are selected from the group consisting of activity codes, sleep and administration of medications, dose of medications, and times of medications.

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50. (New) The one or more databases of claim 15, wherein said one or more data attributes associated with said data point or said skipped measurement value is one or more data identifier.

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51. (New) The one or more databases of claim 50, wherein said one or more data identifiers is selected from the group consisting of maximum analyte values, minimum analyte values, hypoglycemic analyte values, and hyperglycemic analyte values.

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52. (New) The one or more databases of claim 15, wherein said one or more data attributes associated with said data point or said skipped measurement value is one or more subject identifier.

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53. (New) The one or more databases of claim 52, wherein said one or more subject identifiers is selected from the group consisting of a subject code, demographic information, physical characteristic, selected aspects of the subject's medical history, and disease-associated characteristics.